

DATE: March 1, 2002

FROM: Director  
Office of Device Evaluation (ODE)

TO: ODE Review Staff

RE: Blue Book Memo: Fax & E-mail Communication with Industry<sup>1</sup>  
about Premarket Files Under Review A02-01

## Purpose

This memo explains ODE's practices for communicating with industry by fax or e-mail about premarket files under review<sup>2</sup> and the differences in ODE's practices between types of files.

## Background

We have updated our fax and e-mail practices for premarket files under review. Our update recognizes the ubiquitous use of fax and e-mail in business and government communications and allows fax and e-mail responses from industry to contain information used by ODE to reach a final decision about a file under review.

Our updated practices ensure fair and consistent use of fax and e-mail throughout ODE and eliminate unnecessary mail to the DMC<sup>3</sup> by clarifying which fax and e-mail responses from industry do not need to be followed with a copy by mail. These practices also help reduce the burden on industry in accordance with the principles outlined in the guidance, **The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles** <http://www.fda.gov/cdrh/ode/guidance/1332.html> by eliminating the need to respond to many ODE requests twice, first by fax or e-mail, then again by mail.

This memo supersedes ODE's past practices on the use of fax and e-mail for files under review, which were outlined in the "Current Status of the ODE Fax Policy" dated June 9, 1995 and in the sections entitled, "Information Received via Telephone" and "Facsimile Transmission (Fax)" in the Blue Book Memorandum, "Document Control Procedures (I-90)," issued September 26, 1990.

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<sup>1</sup> "Industry" is used in this document to mean IDE sponsors, PMA, PDP, and HDE applicants, and 510(k) submitters.

<sup>2</sup> ODE cannot accept an original file of any kind by fax or e-mail. Original files must be submitted in hard copy. (Electronic submissions require hard copy in addition to the disk or CD.)

<sup>3</sup> DMC- Document Mail Center

## Additional Information Requests

Although unlikely, communication by an unexpected fax or e-mail could risk inappropriate disclosure of information. Therefore, faxes and e-mails should only be sent if you have been authorized by the recipient.

The file's submitter, sponsor or applicant may authorize fax or e-mail communication by a statement to that effect in the cover letter. Including a fax number or e-mail address in the letterhead, or elsewhere in the file, does not provide authorization for FDA to communicate by fax or e-mail. To obtain required authorization, you may do so by phone, fax or e-mail, as long as you document the request and authorization by including a memo of the phone conversation and/or a copy of any fax or e-mail received in the file.

Generally, you should use this disclaimer on all fax and e-mail messages that you send.

“THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.”

You should follow the instructions below for using fax and e-mail to request additional information in each program area. (See also [Table 1.](#)) **For all files, you must place a copy of every request for additional information made by fax or e-mail in the file jacket.**

### 510(k)

If your request for additional information does not stop the review clock, you may make the request by phone, fax, or e-mail.

If your request for additional information stops the review clock, you may use phone, fax, or e-mail to make the request, as long as you include documentation of what was requested (i.e., a copy of the fax or e-mail, or a memo), log the submission out of the division as a Telephone Hold, and send the file to DMC to be placed on hold.

Alternatively, the review division may fax a signed, date-stamped K3<sup>4</sup> letter to the submitter and send the file to DMC to be placed on hold. You must include the letter with the file in order for DMC to mail it to the submitter. Each division should develop a consistent policy for using Telephone Holds and K3 letters.

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<sup>4</sup> K-3 is the “Cannot determine equivalency - need more information” letter.

## **PMA, PDP, HDE & IDE**

You must not use a fax or e-mail request to stop the review clock for a PMA, PDP, HDE, or IDE. However, you may use fax or e-mail to request information that does not stop the review clock, such as:

- administrative information
- explanations of information, studies, or results in the file
- labeling edits

## **Pre-IDE**

Once the original file arrives and is logged into the DMC, you may use fax and/or e-mail for all communications with the party who sent it, provided you have their prior authorization.

## **Early Collaboration Meeting**

You may request additional information by fax or e-mail. See the guidance, **Early Collaboration Meetings Under the FDA Modernization Act (FDAMA)**, <http://www.fda.gov/cdrh/ode/guidance/310.html> for complete information about early collaboration (i.e., agreement and determination) meetings.

# **Additional Information Responses**

If a request for additional information has stopped the review clock, **industry needs to respond by mail to start the clock again.**

For all program areas, when industry is permitted to respond by fax, you should ensure that the sender signs it. **You must place copies of all fax and e-mail industry responses in the file jacket.**

## **510(k)**

If the review clock was not stopped, the submitter should respond to you by fax or e-mail without sending a hard copy to the DMC.<sup>5</sup> If the submitter prefers not to respond by fax or e-mail (e.g., the response is very lengthy or contains information that the submitter prefers not to send by fax or e-mail), he or she may respond by mail to the DMC.

After you have cleared the 510(k), if a hard copy arrives in the DMC, in addition to the fax or e-mail response that you placed in the file, despite your instructions to the submitter not to follow up with a hard copy, you are not obligated to retrieve the file and place the hard copy response in it.

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<sup>5</sup> If you have requested additional information but not stopped the clock and the complete response does not arrive within the amount of time you and the submitter agreed upon, you should contact the submitter and discuss placing the 510(k) on hold to stop the clock.

If the review clock was stopped, the submitter needs to respond by hard copy to the DMC.

### **PMA, PDP, HDE & IDE**

If the clock was not stopped, applicants and sponsors may respond by fax or e-mail. Applicants and sponsors need to follow up a fax or e-mail response with a hard copy to the DMC. We require the hard copy to ensure that a copy of the fax or e-mail is placed in copy 1 (the copy retained in DMC while the application is under review) of the application.

If the clock was stopped, **only a hard copy response to the DMC will re-start the clock.**

### **Pre-IDE**

Industry may respond by fax or e-mail with no hard copy follow up.

### **Early Collaboration Meeting**

Industry needs to respond by hard copy to DMC.

## **Requests for Extensions and Withdrawals**

**Industry needs to send requests for extension or withdrawal, containing an original signature, to the DMC by mail for all program areas.** For 510(k)s and IDEs, industry may notify the review division of their intent to withdraw beforehand as described below. ([See also Table 2.](#))

### **510(k)**

A submitter may notify the review division of his or her intent to withdraw a 510(k) by phone, fax, or e-mail, but he or she must follow up with a written request by mail to the DMC. After being notified by the submitter, the review division should place the 510(k) on hold while awaiting the written request for withdrawal.

A submitter may request an extension for a 510(k) on hold by sending a written request by mail to the DMC.

### **PMA, PDP, & HDE**

Applicants need to send all requests for extension or withdrawal, containing an original signature, to the DMC by mail. No action will be taken until the DMC receives the written request.

### **IDE**

A sponsor may request by fax (but not phone or e-mail) that the review division consider an IDE withdrawn. The review division may act on the faxed request, but

the sponsor must send a written request for withdrawal, containing an original signature, by mail to DMC. See also **Guidance on IDE Policies and Procedures**, <http://www.fda.gov/cdrh/ode/idepolicy.html>.)

### **Pre-IDE**

Requests for withdrawal need to be sent to the DMC by mail. Pre-IDEs are not placed on hold, therefore, extensions do not apply.

### **Early Collaboration Meeting**

Industry needs to send all requests for extensions and withdrawals by mail to the DMC.

## **Final Decision Letters**

Specific restrictions and instructions exist in each program area, as described below. FDA has not established any procedures for e-mailing signatures or date-stamped decisions, therefore, **you must not use e-mail to communicate the approval or clearance decision** to a submitter, applicant, or sponsor. (See also Table 3.)

### **510(k)**

ODE Program Operations Staff (POS) will fax the 510(k) decision letter to the submitter, if the submitter has provided a fax number with the original submission. Additional information (K3) letters are not final decision letters. The review division may fax a date-stamped, additional information letter to the submitter, before properly logging the 510(k) out of the division and sending it to the DMC to be placed on hold.

### **PMA, PDP & HDE**

The review division should fax the signed, date-stamped, approval order to the applicant for an original PMA, PDP or HDE. The division should request that POS fax the letter if the division is not planning to fax it.

POS will fax signed, date-stamped letters for 30-day Notices.

For all other PMA, PDP, and HDE letters, the review division may fax the signed, date-stamped letter to the applicant. Each review division should establish a consistent policy for each type of letter.

### **IDE**

The review division should fax signed, date-stamped IDE disapproval letters. The review division may fax other signed, date-stamped IDE letters, but only if they develop a consistent policy for each type of letter.

**Pre-IDE**

ODE does not issue final decision letters for pre-IDEs, however, the review division may provide comments to the sponsor by phone, fax, e-mail, or letter. The review division is responsible for ensuring that all memos, reviews, letters, faxes, and e-mails are included in the file. Upon completion of the review, the document should be returned to the DMC for filing.

**Early Collaboration Meeting**

POS will fax determination and agreement letters to their sponsors.

Effective date: March 1, 2002

**Table 1 Additional Information Requests and Responses**

<b>File</b>	<b>Request</b>	<b>Response</b>	<b>Reviewer must document with hard copy to the file:</b>
510(k)	Any information, but if need to stop the clock, must use Telephone Hold or K3 letter.	(Clock running) by fax or e-mail - no follow up hard copy. (Clock stopped) only by hard copy to the DMC.	Requests made by fax or e-mail and responses received only by fax or e-mail.
PMA, PDP, HDE	Only information that does not stop the clock.	By fax or e-mail – must follow up with a hard copy to the DMC.	Requests made by fax or e-mail, responses received by fax or e-mail, and follow up copies.
IDE	Only information that does not stop the clock.	By fax or e-mail – must follow up with a hard copy to the DMC.	Requests made by fax or e-mail, responses received by fax or e-mail, and follow up copies.
Pre-IDE	Any information	By fax or e-mail - no follow up hard copy.	Requests made by fax or e-mail and responses received only by fax or e-mail.
Early Collaboration Meeting	Any information	Only hard copy to the DMC.	Requests made by fax or e-mail.

## Table 2 Requests for Extensions or Withdrawal

FILE	REQUEST
510(k)	<p><b>Extension</b> - In writing, containing an original signature, to the DMC by mail.</p> <p><b>Withdrawal</b> - By phone, fax or e-mail. Follow up in writing, containing an original signature, to the DMC by mail.</p>
PMA, PDP, HDE	<p><b>Extension or Withdrawal</b> - In writing, containing an original signature, to the DMC by mail.</p>
IDE	<p><b>Extension</b> - In writing, containing an original signature, to the DMC by mail.</p> <p><b>Withdrawal</b> - By fax, follow up in writing, containing an original signature, to the DMC by mail.</p>
Pre-IDE	<p><b>Extension</b> - Does not apply.</p> <p><b>Withdrawal</b> - In writing, containing an original signature, to the DMC by mail.</p>
Early Collaboration Meeting	<p><b>Extension or Withdrawal</b> In writing, containing an original signature, to the DMC by mail.</p>

### Table 3 Faxing Final Decision Letters

File	Letter	Faxed by POS	Faxed by Review Division
510(k)	all types of final decision letters	POS only	no
PMA, PDP, HDE	approval orders for originals	yes <sup>6</sup>	yes
	30-day Notices	POS only	no
	other final decision letters	no	yes <sup>7</sup>
IDE	disapproval letters	no	yes
	other letters	no	yes <sup>7</sup>
Pre-IDE	ODE does not issue final decision letters	--	--
Early Collaboration Meeting	all final decision letters	POS only	no

<sup>6</sup> If requested by the division, otherwise the division should fax the letter.

<sup>7</sup> Each review division should establish a consistent policy for each type of letter.